

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	David E. Francischelli et al.	Examiner:	Michael F. Peffley
Serial No.:	10/752,135	Group Art Unit:	3739
Filed:	January 6, 2004	Docket No.:	M190.257.101/P-8922.06
Title:	SYSTEM FOR ASSESSING TRANSMURALITY OF ABLATION LESIONS		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This pre-appeal memorandum is presented in support of the Notice of Appeal filed herewith and in response to the Final Office Action mailed February 12, 2008.

1. Claims 21, 22, 25 and 29

Claims 21, 22, 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. US Patent No. 5,443,463 in view of the teachings of Taylor US Patent No. 6,113,592.

Claim 21 includes the features of “an output device in communication with the pad, the output device operatively adapted to indicate continuous transmuralty of the ablated tissue based on the sensed temperature.” Claim 21 also includes the features of “wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue.” Stern teaches a system for coagulating blood with heating electrode disposed on a first side of tissue and temperature sensors disposed on an opposite side of the tissue. The Office Action states that “the Stern et al system is inherently adapted to provide an indication of transmuralty of the lesion (i.e. coagulation zone) since it is monitoring tissue temperature.” Applicants respectfully submit that Stern does not show or made obvious these features.

Stern measures tissue temperature as a function of time and not as a function of area, which is a distinction between Stern and the present claims. The claims specifically set forth “wherein the temperature sensors are in close proximity to each other to effectively detect

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continuous temperature along the second side of the tissue.” Accordingly, it is inappropriate to construe the feature of “continuous temperature” as anything but “continuous temperature along the second side of the tissue.” Instead, the continuous temperature in Stern means continuous temperature as a function of time such as at column 6, lines 18 – 21 (“Allowing the tissue temperature to reach a desired value and maintaining that temperature at the level for an appropriate period of time provides the physician with feedback . . .”). When properly interpreted, Stern’s teachings regarding continuous as a function of time does not meet the terms of the claims.

The device of Stern does not include the ability to detect whether coagulation that has occurred is continuous along the second side of the tissue. The device of Stern takes point measurements of temperature to control heating of tissue. After an appropriate amount of time, the surgeon cuts the tissue with only a guess that continuous coagulation has occurred along the second side of the tissue. Stern does not teach or make obvious the need to indicate continuous coagulation along the second side of the tissue. It merely assumes through a series of physically spaced-apart temperature measurements that enough coagulation has occurred so that tissue will stop bleeding. In contrast, the claim 21 sets forth a system “wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue.”

Applicants have solved the problem inherent in devices such as Stern that point measurements and visual inspection of one side of tissue do not provide a clear indication of continuous ablation. Stern involves a coagulation device and these devices do not recognize that the lack of clear indication of continuity can be a great problem in ablation. Coagulation spreads relatively easily and a miscalculation with the device of Stern leads to only minor bleeding that can be readily repaired because the surgeon is still working in the area with the device in hand. On the other hand, continuous ablation can be more difficult to achieve than continuous coagulation. Further, a lack of continuous ablation along the second side of the tissue can lead to severe problems including an ineffective treatment of arrhythmia or trauma. These effects cannot be readily repaired as with coagulation because they are often not detectable until after

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the surgery is completed. Accordingly, the prior art need not provide a coagulation device of Stern with the measurements and indications of Applicants' ablation device.

Similarly, Taylor does not include features to indicate "wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue."

Because these features are not shown or made obvious in the references separately, the features can not be found in any proposed combination of references. Applicants respectfully submit that claims 21, 22, 25, and 29 are patentably distinguishable and allowable over the combination of Stern and Taylor

2. Claims 1-4, 6-9, 12, 16 and 19

Claims 1-4, 6-9, 12, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern in view of the teaching of Nagai et al. US Patent No. 5,172,949 and Taylor.

Claim 1 also includes the features of "wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue." As discussed in detail above, these features are not shown or made obvious in Stern or Taylor. Nagai does not provide the features missing from Stern and Taylor with respect to claim 1, and it does not recognize or suggest a solution to the problems facing Applicants.

Because the amended features are missing from Stern, Nagai, and Taylor separately, they cannot be found in any proposed combination of the references. Applicants respectfully submit that claims 1-4, 6-9, 12, 16, and 19 are patentably distinguishable and allowable over the combination of Stern in view of Nagai and Taylor.

3. Claims 5, 17 and 18

Claims 5, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern, Taylor, Nagai, and further in view of Chinn US Patent No. 5,647,868. Chinn does not teach or make obvious the features of "wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue." As discussed above, these features are neither shown nor made obvious in either Stern or Nagai.

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Because the amended features are missing from Stern, Nagai, and Chinn separately, they cannot be found in any proposed combination of the references. Applicants respectfully submit that claims 5, 17, and 18 are patentably distinguishable and allowable over the prior art.

4. Claims 10 and 11

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern, Taylor, and Nagai and further in view of Hoffman US Patent No. 4,682,605. Hoffman does not teach or make obvious the features of “wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue.” As discussed above, these features are neither shown nor made obvious in either Stern or Nagai.

Because the amended features are missing from Stern, Taylor, Nagai, and Hoffman separately, they cannot be found in any proposed combination of the references. Applicants respectfully submit that claims 10 and 11 are patentably distinguishable and allowable over the prior art.

5. Claims 23, 24 and 26-28

Claims 23, 24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern and Taylor in view of the teachings of Chinn. Chinn does not teach or make obvious the features of “wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue” as set forth in the independent claim. As discussed above, these features are neither shown nor made obvious in Stern. Chinn further does not teach or recognize the particular problems with thermal ablation and the need to form continuous lesions as Chinn deals with a cooling system.

Because the amended features are missing from Stern, Taylor, and Chinn separately, they cannot be found in any proposed combination of the references. Applicants respectfully submit that claims 22, 24, and 26-28 are patentably distinguishable and allowable over the prior art.

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CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-29 are all in a condition for allowance and requests reconsideration of the application and allowance of all pending claims.

Any inquiry regarding this Request should be directed to Rudolph P. Hofmann at Telephone No. (612) 573-2010, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

David E. Francischelli et al.,

By their attorneys,

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